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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

6751 Steger Road
Cincinnati, Ohio 45237

February 12, 1999

WARNING LETTER
CIN-WL-99-7

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Peter A. Diehl, President and CEO
Diehl, Inc.
24 N. Clinton Street
Defiance, Ohio 43512

Dear Mr. Diehl:

An inspection of your Low Acid Food processing plant was conducted by investigators of the Food and Drug Administration on August 10 through September 22, 1998. At the conclusion of the inspection you were presented with a Form FDA-483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Parts 110 and 113. These sections cover the Good Manufacturing Practices for food processing, Section 110 and Low Acid Canned Foods Manufacturing Practices for food processing, Section 113. Because of these deficiencies, the evaporated, condensed, and filled milk products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act).

Our investigation revealed the following:

Your firm has not maintained an adequate separate process deviation file which contains a listing of the batches of your milk products that have not been processed per the scheduled process, together with the corrective actions taken. Any batch that does not meet the requirements for all critical factors shall be set aside for evaluation by the processing authority, or for reprocessing or destruction (21 CFR 113.89). In fact, you were not aware of the specific process deviations until the FDA investigators brought them to you attention. For example:

A review of your processing records for your canned milk products from January 1, 1998 to August 31, 1998 revealed that there was a lack of control of critical factors in your manufacturing process, e.g., [redacted] for milk in #10 cans, [redacted] for milk in pouches, cook times for your milk products, and the failure to submit process deviations to your process authority for evaluation.

Four (4) lots of 97 fluid ounce pouches of evaporated milk were found to have cook times less than the scheduled process minimum requirement of [redacted] minutes and process temperatures lower than the temperature indicated on the temperature recording charts.

The chart recorder and the computer display on the [redacted] units did not correspond to the mercury-in-glass (MIG) thermometer. The chart recorder or computer display may show a reading up to $3^0$ F higher than the MIG thermometer.

The processes for nine (9) days production for the 97 fluid ounce pouches of evaporated milk exceeded the maximum fill weight, a [redacted] in your manufacturing process.

When pouch weights for your milk products exceeded the maximum fill weight, only the pouches on the filler were reprocessed even though pouch weights that can be traced back to the previous acceptable fill weight should have been treated as suspect deviations from fill weight, [redacted]

There were fifty (50) instances in which the recorder charts showed less than the [redacted] minutes required cook time for milk in #10 cans.

Your firm failed to have processing and production records reviewed by a representative of plant management who is qualified by suitable training or experience, to ensure that the records are complete and to ensure that the product received the scheduled process in accordance with 21 CFR 113.100(b).

At the time of the FDA inspection of your facility ( i.e., as of September 18, 1998) none of the process deviations discussed above had been identified and as a result the process deviations had not been submitted to a process authority for evaluation.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and on the Form FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA.

We received your firm's letter of response to the Inspectional Observations (Form FDA 483) presented to management at you firm at the close of the FDA inspection. The letter was dated December 29, 1998. The changes you indicate you have made appear adequate to correct some but not all of the objectional conditions pointed out to you. For example, we agree with the corrective action your firm has taken to stop using untreated river water as cooling water in your [redacted] Sterilizers.

However, your letter did not provide sufficient documentation that all of the deviations pointed out to you were corrected and that your firm has initiated appropriate monitoring and control procedures to ensure compliance with the mandatory provisions of 21 Code of Federal Regulation (CFR) 108.35 and 113.

Please refer to Attachment A of this Warning Letter for a continuation of the FDA response to your December 29, 1998 letter. Your letter will be made a permanent part of the Establishment Inspection Report of your firm.

It is your responsibility to insure that all foods manufactured and distributed by your firm meet the requirements of the Act and conform to the mandatory provisions of the low-acid canned food regulation. Failure to take such action may result in regulatory action such as seizure, and/or imposition of the requirement to obtain a temporary emergency permit as set forth in 21 CFR 108.5 without further notice.

Sincerely,

Henry L. Fielden
Acting District Director
Cincinnati District

Attachment:
A- FDA Comments